

COCA Call Information

- For the best quality audio, we encourage you to use your computer's audio.
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Update on Ebola Diagnostics at the State and Federal Level in the United States

Clinician Outreach and Communication Activity (COCA) Webinar

Thursday, December 19, 2019

Continuing Education

All continuing education for COCA Calls are issued online through the CDC Training & Continuing Education Online system (<http://www.cdc.gov/TCEOnline/>).

Those who participated in today's COCA Call and who wish to receive continuing education should complete the online evaluation by **January 20, 2020**, with the course code **WC2922**. The access code is **COCA121919**. Those who will participate in the on demand activity and wish to receive continuing education should complete the online evaluation between **January 20, 2020**, and **January 21, 2022**, and use course code **WD2922**. The access code is **COCA121919**.

Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Continuing Education Disclaimer

- In compliance with continuing education requirements, CDC, our planners, our presenters, and their spouses/partners wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.
- Planners have reviewed content to ensure there is no bias.
- Content will not include any discussion of the unlabeled use of a product or a product under investigational use.
- CDC did not accept commercial support for this continuing education activity.

To Ask a Question

- Using the Webinar System
 - Click on the **Q&A** button in the Zoom webinar system.
 - Type your question in the **Q&A** box.
 - Submit your question.
 - Please do not submit a question using the chat button.
- For media questions, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc.gov.
- If you are a patient, please refer your questions to your healthcare provider.

Objectives

- Discuss procedures for assessing ill travelers returning from the outbreak area, including consultation with relevant public health authorities.
- Describe CDC's role in providing technical support and testing approval for persons under investigation (PUI) for Ebola virus infection.
- Review the procedure for reporting and consulting on a suspected case of Ebola in the United States.
- Discuss considerations and limitations for domestic use of novel rapid diagnostic tests for Ebola.
- Discuss how to coordinate between clinicians, state health departments, and CDC as it pertains to domestic Ebola preparedness and diagnostics.

Today's First Presenter

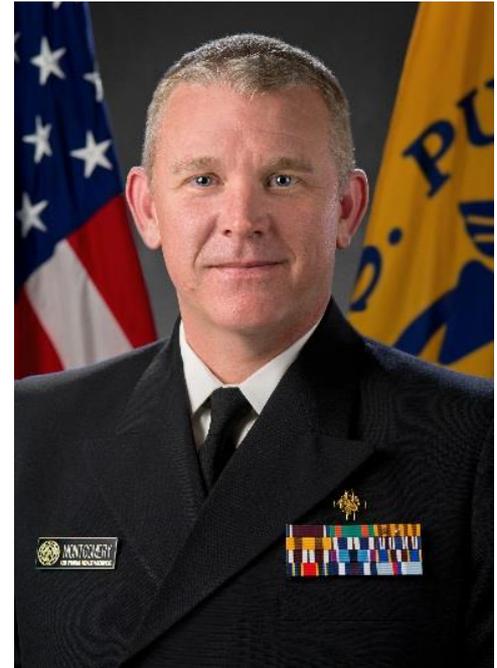
CAPT Joel Montgomery, PhD, USPH

Chief

Viral Special Pathogens Branch

Division of High-Consequence Pathogens and
Pathology

Centers for Disease Control and Prevention



Today's Second Presenter

Julie Villanueva, PhD

Chief

Laboratory Preparedness and Response Branch
Division of Preparedness and Emerging Infections
Centers for Disease Control and Prevention



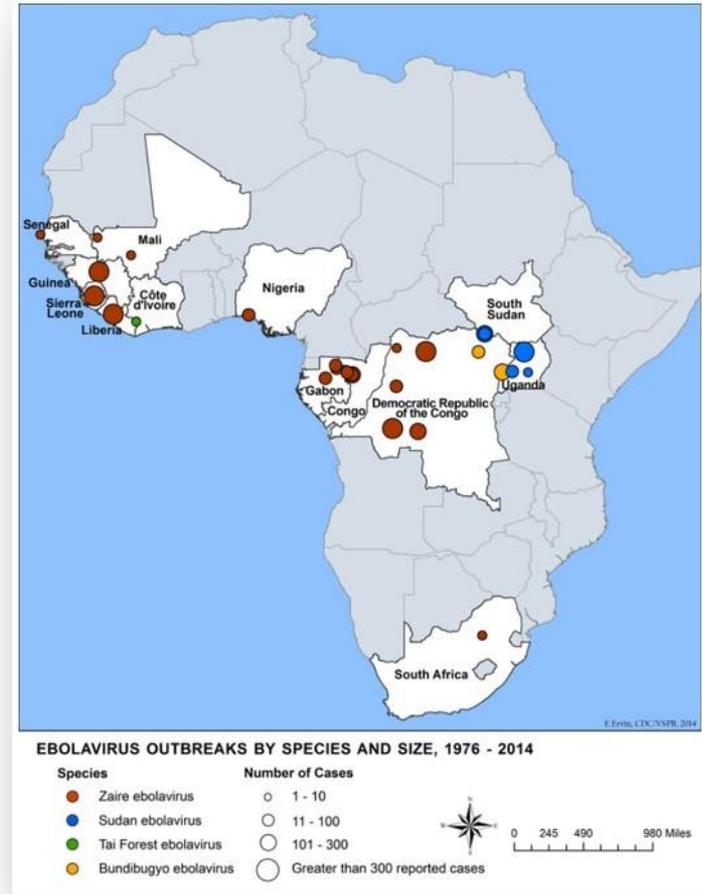
Overview

- Overview of Ebola outbreak in the Democratic Republic of the Congo (DRC)
- Process for confirmatory testing of suspected Ebola cases in the US
- Overview of the US Laboratory Response Network (LRN) functions
- Ebola rapid diagnostic test (RDT): intended use, limitations, and considerations

Overview of Ebola and the Outbreak in the Democratic Republic of the Congo (DRC)

Background

- Ebola virus disease (EVD) is a deadly disease caused by infection with one of four viruses within the genus *Ebolavirus*, family *Filoviridae*
- First discovered in 1976 near the Ebola River in DRC
- Outbreaks in people have occurred sporadically in Africa over the past several decades
- Natural reservoir unknown; likely bats



Species of *Ebolavirus*

- 6 species of Ebolavirus
 - *Zaire ebolavirus*
 - *Sudan ebolavirus*
 - *Bundibugyo ebolavirus*
 - *Tai Forest ebolavirus*
 - *Reston ebolavirus*
 - *Bombali ebolavirus*
- All species but Reston and Bombali are known to cause disease in humans

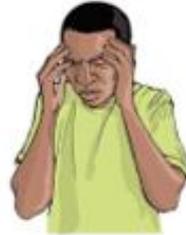


Signs and Symptoms

- **Signs and symptoms of Ebola**

- Fever
- Severe headache
- Fatigue
- Muscle pain
- Rash
- Abdominal pain
- Vomiting
- Diarrhea
- Unexplained bleeding
- Miscarriage

Headache



Fever



Feeling tired and weakness



Red eyes



Joint and Muscle pain



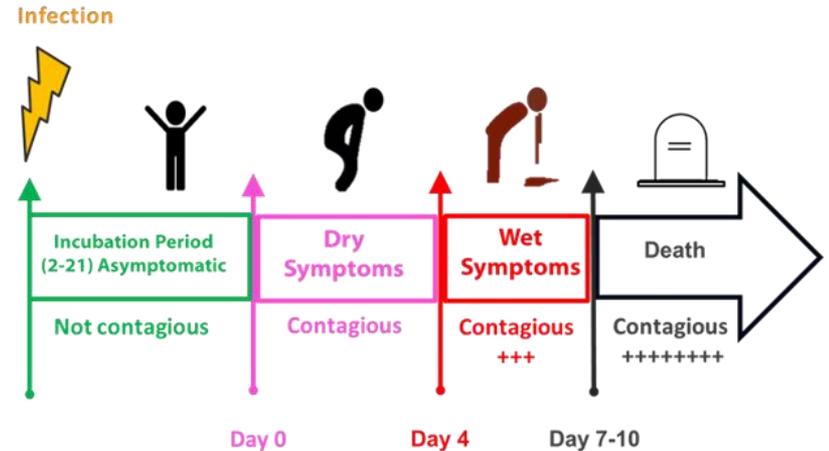
Nausea, stomach pain



- **A person infected with Ebola virus is not contagious until symptoms appear**

Progression of EVD

- **Incubation period: time from exposure to when signs or symptoms appear**
 - 2–21 days (average 8–10 days)
 - A person infected with Ebola cannot spread it before symptoms develop
- **Wet symptoms develop ~ day 4 of illness**
- **Patient becomes increasingly contagious as the illness advances**
- **Without treatment, death usually occurs 7–10 days after illness onset**
- **Concentration of Ebola virus in the body is highest at time of death**



2018 Ebola Outbreak in Eastern DRC



- DRC Ministry of Health confirmed an Ebola outbreak in North Kivu province on August 1, 2018
- Species: Ebola virus (*Zaire ebolavirus*)
- WHO declared the outbreak a Public Health Emergency of International Concern on July 17, 2019

EVD Cases Reported in the Past 21 Days by Health Area, 10 December 2019

From 20 Nov to 10 Dec:

- 42 Confirmed Cases
- 4 Health Zones
- 15 Health Areas

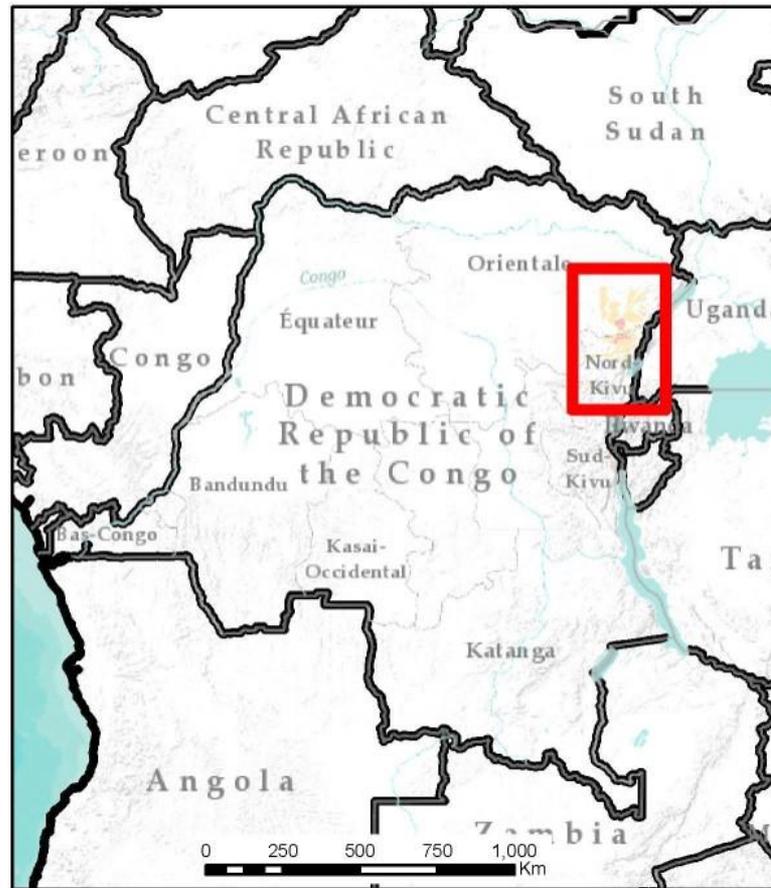
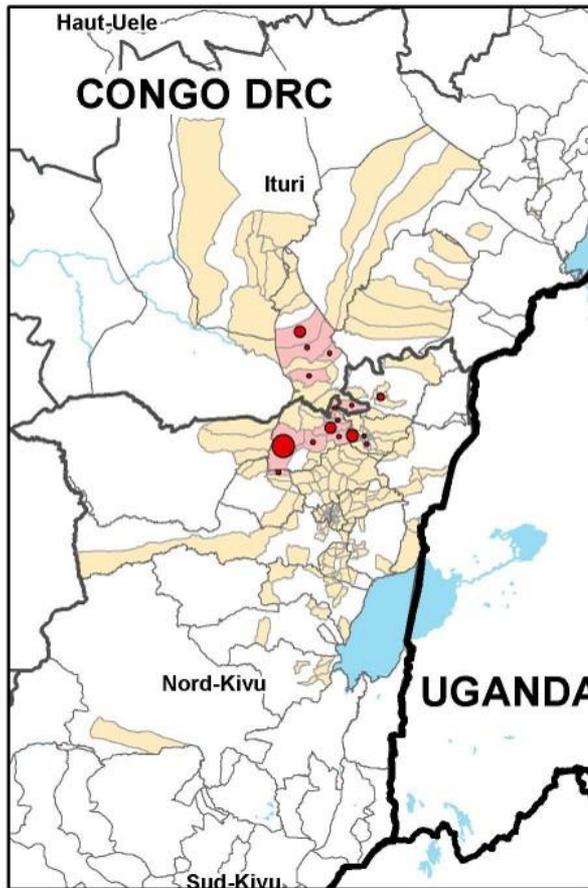
Data as of 10 December 2019
Sources: DRC MOH, WHO, CDC

EVD Cases

- 1
- 5
- 10

Health

- Case in Past 21 Days
- Case Before Past 21 Days
- Health Zones (DRC)
- Districts (Uganda)
- Provinces
- Countries



Ebola by the Numbers

- Second largest Ebola outbreak ever recorded
- Largest Ebola outbreak in DRC
- As of December 18, 2019:
 - Cases: more than **3,300**
 - Deaths: more than **2,200**



Challenges

- Porous internal and external borders
- High population mobility
 - Extensive movement in and out of North Kivu and Ituri provinces
- Security issues, including ongoing violence aimed at Ebola response efforts
- Misperceptions that lead to mistrust



Risk of Spread to the US

- Risk of global spread of Ebola, including to US, is currently low
- No direct flights between DRC and the US. Fewer than 16,000 people a year travel to the US from DRC.
- People at risk:
 - Travelers going to the outbreak area in eastern DRC
 - Those who have contact with an Ebola-infected person (living or deceased)



Process for Testing of Suspected Ebola Cases in the United States

Diagnosis of Ebola in a Person Under Investigation



- **Required for diagnosis:**
 - **A combination of compatible symptoms AND potential exposure in the past 21 days**
- **Early diagnosis may be difficult as symptoms can appear similar to other more common diseases, such as malaria, dengue, influenza, and typhoid**

Testing for Ebola in a Person Under Investigation

- If a person shows symptoms consistent with Ebola AND has had a possible exposure to Ebola virus within the past 21 days
 1. Isolate the person (separate from other people)
 2. Notify state and local public health authorities
 3. If recommended by public health authorities, collect blood samples for laboratory testing
 - a. Use appropriate infection prevention and control precautions
 - b. For additional guidance, refer to **Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing in the United States**: <https://www.cdc.gov/vhf/ebola/>

Testing for Ebola: Considerations

- Facilities that collect and handle specimens from suspect Ebola cases should ensure biosafety protocols for the safe handling and disposal of all potentially infectious materials to avoid risk of exposure
- Polymerase chain reaction (PCR) is one of the most commonly used diagnostic methods because of its ability to detect low levels of Ebola virus
- It may take up to 3 days after symptoms start for the virus to reach detectable levels
 - Samples collected within 3 days after symptom onset may yield false-negative results

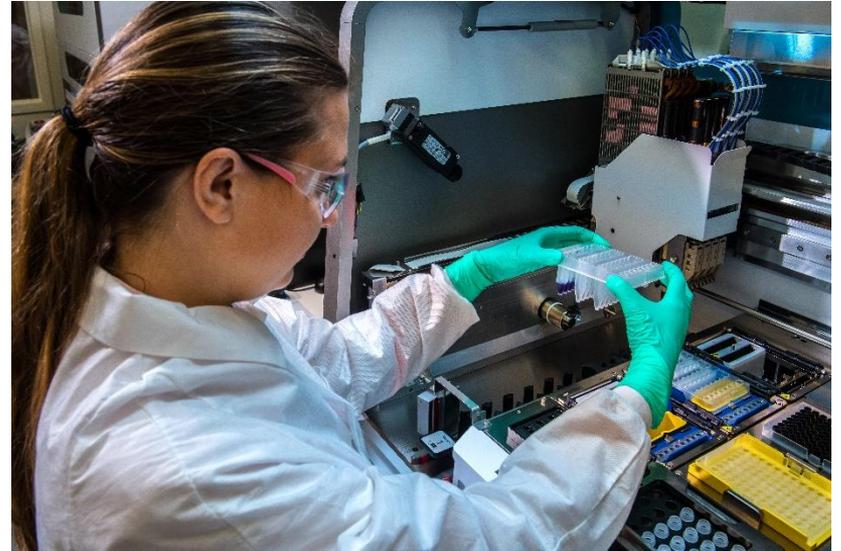
Clinical Inquires

- **Clinicians with concerns about a suspect EVD patient should first contact their state or local health authorities**
- **Calls from clinicians to CDC regarding suspect EVD patients are referred to the state/local health departments first**
- **Since August 2018, CDC has received 49 clinical inquiries regarding ill travelers from DRC or surrounding countries**
 - **1 patient recommended for Ebola testing; tested negative for Ebola**

Overview of the US Laboratory Response Network (LRN)

Laboratory Response Network

- Network of laboratories that can respond to biological and chemical threats, and public health emergencies
- Currently 69 LRN laboratories in 49 states capable of conducting Ebola virus testing
 - Real-time reverse transcriptase polymerase chain reaction or rRT-PCR

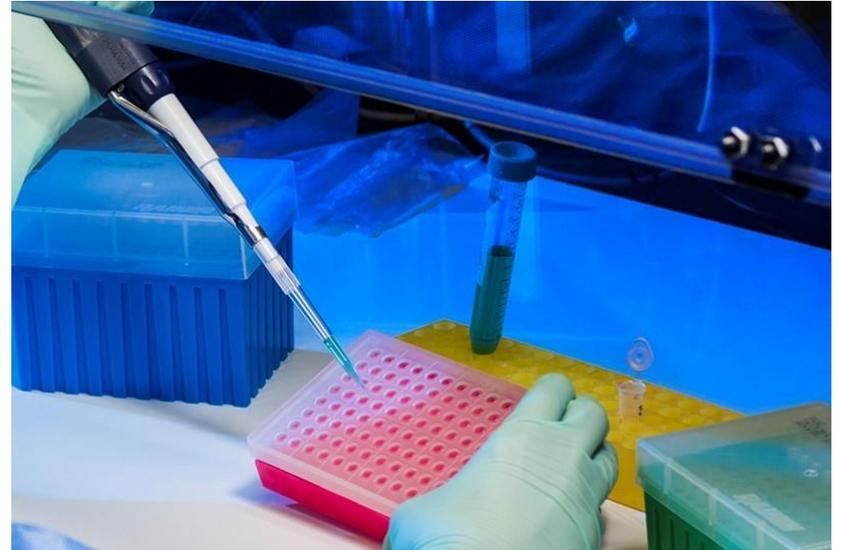


LRN Testing and Ebola Algorithm

- There are 2 tests used by LRN laboratories to detect Ebola virus RNA, species *Zaire ebolavirus*:
 - CDC Ebola Virus NP rRT-PCR Assay
 - CDC Ebola Virus VP40 rRT-PCR Assay
- Authorized for use by the FDA under Emergency Use Authorization
- Only conducted on specimens for person under investigation for Ebola virus disease (EVD)

Test Results

- **Negative results:** Ebola virus RNA not detected
- **Inconclusive results:** test cannot be interpreted
- **Presumptive positive results:** Ebola virus RNA detected



Confirmatory Testing at CDC

- All specimens that test presumptive positive by the Ebola virus rRT-PCR assay at an LRN laboratory must be forwarded to CDC for confirmatory testing
- Molecular testing at CDC is required in order to confirm the presence of Ebola RNA and to differentiate between species of *Ebolavirus*



Ebola Rapid Diagnostic Tests (RDT): Intended Use, Limitations, and Considerations

OraSure OraQuick® Ebola Rapid Antigen Test

- In October 2019, the US Food and Drug Administration allowed marketing of the first Ebola rapid diagnostic test (RDT) for the detection of Ebola virus in both symptomatic patients and deceased individuals
- This RDT is an antigen-capture lateral flow immunoassay capable of detecting antigens of species including *Zaire ebolavirus*, *Bundibugyo ebolavirus*, and *Sudan ebolavirus*



RDT Intended Use

- **Originally developed as a tool for rapid presumptive diagnosis of Ebola in outbreak settings**
- **Has utility for low resource areas where access to rapid confirmatory testing is a challenge**
- **Not intended to be used for general Ebola infection screening or testing of asymptomatic individuals or those without risk factors and compatible symptoms of EVD**

Limitations

- The OraQuick® Ebola rapid Antigen Test has been shown to be capable of detecting antigens for three species of Ebolavirus: *Zaire ebolavirus*, *Bundibugyo ebolavirus*, and *Sudan ebolavirus*—but it cannot differentiate between these three species
- Results, whether positive or negative, must be verified through real-time reverse transcriptase polymerase chain reaction testing (rRT-PCR) at an LRN laboratory or CDC

Limitations (continued)

- **Results from an Ebola RDT alone should not be used to:**
 - **Rule out Ebola infection in a person with compatible symptoms and epidemiologic risk factors for Ebola**
 - **Determine the type or use of infection prevention and control (IPC) measures, including personal protective equipment (PPE) use by healthcare workers when managing a patient with compatible symptoms and epidemiologic risk factors for Ebola**
 - **Screen asymptomatic returning travelers that may have been exposed to Ebola while traveling or working internationally**

Considerations

- **Healthcare providers concerned about a patient with potential Ebola virus infection should first contact their local or state public health authorities before any testing is performed**
- **Interpretation of RDT results should be done with caution and in consultation with relevant public health authorities**
- **RDT results should not be used to rule out Ebola infection or to determine the use or type of infection prevention and control precautions when managing a patient with compatible symptoms and epidemiological risk factors**

Conclusions and Recommendations



Recommendations

- **All RDT results (positive and negative) are presumptive and must be verified through rRT-PCR testing available at 69 LRN laboratories in 49 states and at CDC**
- **The OraQuick® Ebola Rapid Antigen Test should be used only in circumstances where more sensitive molecular testing at LRN laboratories or CDC is unavailable**
- **Healthcare providers who may be concerned about a patient with potential Ebola virus infection should first contact their local or state public health authorities**
- **RDT results alone should not be used to rule out Ebola virus infection or to determine the use or type of infection prevention and control precautions when managing a patient with compatible symptoms and epidemiologic risk factors**
- **CDC is available to provide consultation, technical assistance, and confirmatory testing as necessary**

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- If you are a patient, please refer your questions to your healthcare provider.

Today's Webinar Will Be Available On-Demand

When: A few days after the live call

What: Video with closed captioning

Where: On the COCA Call webpage at

https://emergency.cdc.gov/coca/calls/2019/callinfo_121919.asp

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Upcoming COCA Call

Topic: “Patient-Centered Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics: HHS Guidance

Date: Thursday, January 30, 2020

Time: 2:00-3:00 PM EST

COCA Products & Services



The graphic for COCA Call features a blue background. On the left, there are four circular icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle. To the right of these icons, the text 'COCA Call' is written in large white letters, and 'CDC Clinician Outreach and Communication Activity' is written in smaller blue letters below it.

COCA Call
CDC Clinician Outreach
and Communication Activity

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.



The graphic for COCA Learn features a green background. On the left, there are four circular icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle. To the right of these icons, the text 'COCA Learn' is written in large white letters, and 'CDC Clinician Outreach and Communication Activity' is written in smaller green letters below it.

COCA Learn
CDC Clinician Outreach
and Communication Activity

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.



The graphic for Clinical Action features a red background. On the left, there are four circular icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle. To the right of these icons, the text 'Clinical Action' is written in large white letters, and 'CDC Clinician Outreach and Communication Activity' is written in smaller red letters below it.

Clinical Action
CDC Clinician Outreach
and Communication Activity

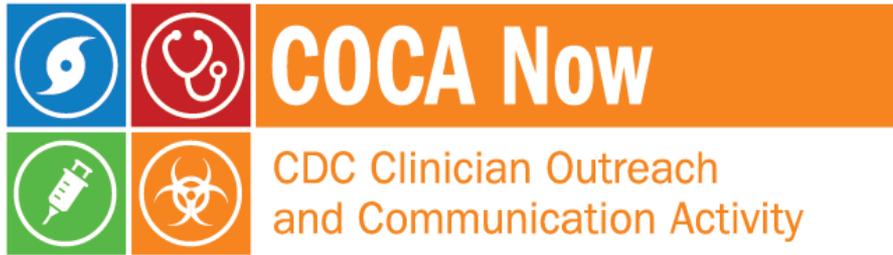
As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

COCA Products & Services

The logo for COCA Digest features a 2x2 grid of icons: a blue circle with a white eye, a red circle with a white stethoscope, a green circle with a white syringe, and an orange circle with a white biohazard symbol. To the right of these icons is a purple horizontal bar containing the text "COCA Digest" in white, and below that, the text "CDC Clinician Outreach and Communication Activity" in purple.

COCA Digest
CDC Clinician Outreach
and Communication Activity

Monthly newsletter that provides updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.

The logo for COCA Now features a 2x2 grid of icons: a blue circle with a white eye, a red circle with a white stethoscope, a green circle with a white syringe, and an orange circle with a white biohazard symbol. To the right of these icons is an orange horizontal bar containing the text "COCA Now" in white, and below that, the text "CDC Clinician Outreach and Communication Activity" in orange.

COCA Now
CDC Clinician Outreach
and Communication Activity

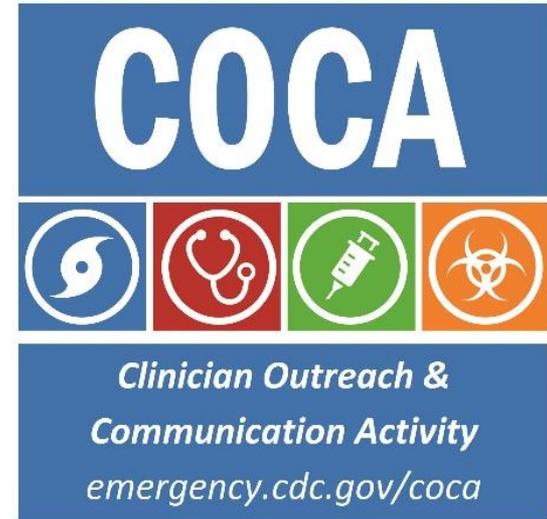
Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.



CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

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- **Receive information about:**
 - **Upcoming COCA Calls**
 - **Health Alert Network (HAN) messages**
 - **CDC emergency response activations**
 - **Emerging public health threats**
 - **Emergency preparedness and response conferences and training opportunities**



<http://emergency.cdc.gov/coca>

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The screenshot shows the Facebook profile for COCA (CDC Clinician Outreach and Communication Activity). The profile picture features a diverse group of healthcare professionals. The cover photo shows a group of six people, including nurses and doctors, smiling. The page name is "CDC Clinician Outreach and Communication Activity - COCA" with the handle "@CDCClinicianOutreachAndCommunicationActivity". The page is categorized as a "Government Organization in Atlanta, Georgia". It has 21,420 likes and 21,217 followers. A recent post from October 31, 2017, at 1:18pm, announces a COCA Call on November 7, 2017, at 2:00PM, where clinicians can earn free CE. The address listed is 1600 Clifton Rd NE, Atlanta, Georgia 30333.

COCA

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October 31 at 1:18pm
Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM.

About
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Thank you for joining us today!



<http://emergency.cdc.gov/coca>

For more information, contact CDC
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